AMERICAN ACADEMY™
OF OPHTHALMOLOGY

ADVISORY OPINION OF THE CODE OF ETHICS

Subject:	Informed Consent
Issues Raised:	What are the professional responsibilities that govern discussion of risks, benefits, and alternatives when medical or surgical treatments are proposed?
Applicable Rules:	Rule 1. Competence Rule 2. Informed Consent Rule 3. Research and Innovation Rule 4. Other Opinions Rule 9. Medical and Surgical Procedures Rule 10. Procedures and Materials Rule 13. Communications to the Public

Background

When medical and surgical procedures are proposed, both ethical principles and the law require discussion of significant associated risks. Clearly, an ophthalmologist must understand and conform to the minimum required by applicable law. In some states, a community standard is used by which a physician must disclose any information about risks and other factors that the average prudent physician in the community would disclose. Most other states set a higher standard, requiring disclosure of all information possessed by the doctor that a reasonable patient would find significant in deciding whether to undergo a procedure. Although legal requirements are an important benchmark on which to build, they should be regarded as a minimum standard that is routinely exceeded by practice of good professional ethics.

From the ethical perspective, any risks or potential complications that are sufficiently common or significant that they might reasonably influence the patient's decision whether to proceed with the proposed treatment must be disclosed. Exclusions may include very minor, rare, or inconsequential risks. Similarly, if a risk is readily apparent to people of common sense, then discussion can reasonably be excluded unless the physician has reason to believe that such a disclosure is necessary or appropriate in view of the unique needs of a particular patient. Essentially, the physician must explain the rationale for the treatment, significant benefits, risks, and reasonable alternatives to the treatment proposed in language that the patient can understand.

When a patient is too young to legally consent to treatment, or when a patient lacks the capacity to comprehend and decide independently, the informed consent must be obtained from a surrogate who is legally entitled to provide consent on the patient's behalf. The same procedure for explaining the rationale, risks, benefits, and alternatives should be followed with a guardian or surrogate.

The following cases illustrate potential shortcomings in the informed consent process that may arise, despite the practitioners' self-assessments that they practice ethically. It is important for all ophthalmologists to examine their approach to informed consent in order to best uphold the rights of patients as plans for medical or surgical treatment are discussed.

First Inquiry

Facts - Mr. Harrison is a 50-year-old drill press operator. He had not been seeing well for the previous 4 months and went to Dr. D for help. Dr. D found normal acuity in both eyes but elevated intraocular pressures (30 mmHg in the right eye and 25 mmHg in the left), with glaucomatous damage to both optic nerves (severe in the right and moderate on the left) and marked visual field loss. In the absence of other ocular abnormalities, Dr. D diagnosed primary open-angle glaucoma. He explained the nature of glaucoma in detail and why the intraocular pressure should be reduced if vision were to be preserved. He also described several forms of treatment, stating that eye drops are commonly used first and that surgery is subsequently employed if medical treatment is not sufficient to control the disease. The discussion took 10 minutes.

When Mr. Harrison asked, "What do you think I should do," Dr. D prescribed timolol 0.5% twice a day and instructed Mr. Harrison to return in a week. He neglected to ask Mr. Harrison whether he had a history of heart or respiratory problems. At the second visit, the intraocular pressures were significantly lower, but Mr. Harrison complained that on four recent occasions he had experienced severe shortness of breath and was worried about his asthma returning, even though he had not experienced similar episodes for a long time. When Dr. D listened to his patient's chest, he instructed him to discontinue the timolol without other comment. It was now clear to Dr. D that the patient had a history of asthma. Dr. D had failed to mention asthma as a potential contraindication to the recommended drug therapy and to disclose the consequences of the omission. Mr. Harrison now suspects that he had had an adverse reaction to the prescribed medicine, and he has asked if Dr. D acted ethically.

Resolution - Dr. D appears to have evaluated the ophthalmic problem properly and to have made the correct diagnosis (glaucoma). However, he failed to thoroughly assess the patient's medical history, which was a serious omission in his informed consent process. He described the nature of glaucoma and the basic options for treatment, and he prescribed an appropriate drug. Although the consequences of nontreatment were mentioned, alternative drugs and their different benefits and risks were never discussed. Since timolol can exacerbate asthma and chronic obstructive pulmonary disease and can cause potentially serious cardiac complications, this was a serious omission that deprived Mr. Harrison of important information that may have affected his decision about the treatment recommendation. Although Dr. D also failed to mention alternative medicines and their risks and benefits, he was not obligated to enumerate every conceivable medicine or rare side effect. Nevertheless, it was an important omission to prescribe timolol without first asking questions that would identify contraindications and without discussing several common and easily identified side effects. Common alternatives, such as prostaglandin analogs, were not mentioned. These omissions are deficiencies in the process of obtaining informed consent for treatment, as required by Rule 2 of the Code of Ethics.

Second Inquiry

Facts - Dr. A makes it his practice to discuss a proposed procedure with each patient before surgery. He asks cataract patients questions about functional needs and how the problem has affected their lifestyle. After an appropriate examination, he explains why cataract surgery is warranted. When observation may be appropriate, he explains nonsurgical management. If he recommends surgery, he discusses the rationale in common language as well as poor outcomes, risks of anesthesia, and other significant complications. He indicates that there are some very uncommon complications but does not provide an exhaustive list. He gives each patient a chance to ask questions, but he does not provide printed information. For most

elective cases, each patient is instructed to think the matter over and call the office to schedule surgery. When patients elect to have surgery, he performs his standard procedure: phacoemulsification through a temporal incision with a monofocal foldable lens implant. Dr. A has inquired whether his procedure is consistent with the Code of Ethics.

Resolution - In many respects, Dr. A's procedure is an excellent model of an informed consent process, apparently meeting both ethical and legal requirements. First, he fulfills the requirements that a physician explain in understandable language the nature of the disorder, its prognosis without treatment, the rationale and risks of treatment, and nonsurgical alternatives. Dr. A also includes a discussion of living needs, allowing a more meaningful assessment of indications for surgery or continued observation. Second, the patient must understand the information: Dr. A asks questions to assess whether the patient understands important elements of the discussion. Third, the patient must voluntarily give consent. Dr. A understands that at the emotionally charged moment of considering surgery, a patient's abilities for rational decision making may be compromised. It is therefore particularly helpful that Dr. A gives a patient time to consider a proposed treatment outside the environment of the doctor's office. The fact that Dr. A does not give the patient written information is unimportant; it is the quality of open communication and understanding that matters. Likewise, although it is advisable to have the patient sign a written consent for risk-management reasons, it is not essential from a purely ethical viewpoint if the patient has given a careful and informed consent.

One crucial element that Dr. A does not mention is alternatives to the “standard” surgical procedure that he offers. Does Dr. A always perform only one specific technique and use only one type of lens? Other surgeons in his community may offer toric or presbyopia-correcting lenses. They also might alter their technique to avoid lenses that may be less desirable or contraindicated in some clinical situations, depending on the patient’s needs and associated conditions. If a careful examination and assessment of the patient’s visual needs and expectations reveal that the patient is a candidate for premium “intraocular lenses,” he should advise the patient of this fact so that the patient can consider all reasonable options. Although an ophthalmologist often helps the patient by recommending a particular course of action, the patient should not be denied the opportunity to consider the advantages and disadvantages of important alternatives, even if access to them might require referral to another ophthalmologist.

Third Inquiry

Facts - Mrs. Russell, a retired schoolteacher, had a cataract operation performed OD by Dr. B, a Fellow of the Academy. Her preoperative acuity was OD 20/25 and OS 20/30. Vitreous loss occurred during the procedure, although no vitrectomy was done. Iridocyclitis and vitritis ensued, followed by a retinal detachment. Two reattachment procedures were then unsuccessful because of proliferative vitreoretinopathy. Mrs. Russell is angry about the outcome of her surgery, and she filed a legal claim that she was not informed of the risk of these complications and would have declined the original procedure had she been aware. It was subsequently discovered that Dr. B never discussed with Mrs. Russell the potential risks and benefits of surgery and that his nurse had asked her to sign a long consent document containing technical language about surgical risks including vitreous loss, iridocyclitis, and retinal detachment on the day of the procedure. Mrs. Russell asked no questions and signed the form. She has asked the Academy whether Dr. B acted unethically.

Resolution - Dr. B acted unethically for several reasons. First, for a retired patient with modest visual impairment such as Mrs. Russell, it is particularly important to ensure that the patient understands the nature of cataract and alternatives to the proposed surgery, including observation, unless there is some compelling need for surgery. (This presupposes that the

surgeon has made a judgment regarding medical need: see Rule 10 of the Code of Ethics, “Procedures and Materials.”) In this case, it appears that a discussion about the need for surgery never occurred. Second, merely presenting a technically worded consent document and asking for a signature on the day of surgery would rarely satisfy the ethical obligation to obtain informed consent. Many studies have shown that in the emotionally charged environment of a health care facility, together with the complex wording of such forms, patients do not adequately assimilate the information. Because of the lack of understanding, this is not *informed* consent. It is Dr. B's obligation to convey understandable information about the risks, benefits, and alternatives to surgery and to confirm that the patient understands what they mean. This kind of personal communication also improves doctor-patient relations, which in itself can be helpful in avoiding legal claims. Finally, Dr. B's conduct also fails to satisfy the "voluntary" criterion of informed consent and could be considered coercive. If a patient is scheduled for elective surgery and is advised of the risks of surgery for the first time on the day of the procedure, the process fails as a true decision point on whether to proceed. Patients might feel obliged to cooperate with an initiative already in progress rather than make an independent decision to have surgery.

It must be stressed that failure to obtain adequate informed consent is a serious ethical violation, even if there is no harm or poor outcome. Surgical success, no matter how good the result, is never a justification for failing to obtain informed consent. The law supports this concept in a majority of states, in which legal claims can be based on inadequate informed consent even in the absence of injury. Dr. B has also clearly violated Rule 2 of the Code of Ethics requiring informed consent. In addition, Dr. B’s management of the surgical complication raises concerns: the physician should be competent to manage complications or refer patients to others as required by the condition. In this respect, Dr. B may have violated Rules 1 and 4 of the Code of Ethics through lack of competence to manage the vitreous loss and failure to make a timely referral for subspecialty management.

Fourth Inquiry

Facts - Mr. Welter is a 72-year-old retired engineer who noted decreased vision in both eyes that hampered his driving for several months, especially in the morning and evening. His internist recommended that he see an ophthalmologist for assessment of his vision as well as his retina because he was being treated for type 2 diabetes for the last 8 years.

He consulted Dr. J, a busy comprehensive ophthalmologist, who is a Fellow of the Academy and has a thriving cataract and refractive surgery practice. Mr. Welter was impressed by Dr. J.’s advertising claims that virtually all his patients were able to see without glasses following surgery.

A preoperative eye exam revealed visual acuity of 20/40 and 20/70, with a poor view to the retina due to diffuse posterior subcapsular opacities, that were greater in the left eye than the right. During a brief discussion with one of Dr. J.’s staff, Mr. Welter was advised that cataract removal with placement of IOL would greatly enhance his vision. He was presented with several surgical options/packages (basic, precision, and premium) which varied according to IOL type, astigmatism correction, and laser-assisted surgery. A surgical counselor asked him for a decision before he left the office. The patient was overwhelmed by the newly discovered diagnosis of cataract, the need for surgery, and the nuances of the packages, the nomenclature of basic versus premium, and what the added expense would cover. He explained to the staff that he needed time to consider the options. He was given 24 hours to think about it if he wanted surgery the following week. If he took longer with his decision, the surgery would need to be postponed to the following month. Because of his compromised activities, he felt it necessary to proceed with surgery as soon as possible. Upon further discussion, he remained confused about the differences between the packages. The basic

package included a standard incision with a “blade”, removal of the cataract, followed by insertion of a basic insurance-approved single-focus lens. The precision package included a laser-assisted incision and astigmatism correction; the premium package included a “premium lens” in addition to the laser-assisted incision, ensuring with 95% certainty that he would not require glasses at any distance postoperatively.

Mr. Welter chose the premium package, and his surgery was performed in both eyes within the following 3 weeks. Postoperatively, his vision was complicated by macular edema, and diabetic retinopathy was noted on postoperative investigation, which accounted for his level of vision following surgery. Moreover, as an astute observer, he noted loss of contrast (a possibility of which he was not informed) and acuity that was only partially correctable with glasses, a meaningful loss for someone who was an engineer. Was Dr. J in violation of his ethical duty to Mr. Welter?

Resolution - There are several ethical issues raised in this inquiry. First, it is the physician’s responsibility to ensure that patients have the information and time to understand their condition and proposed treatment to make an informed consent. Dr. J’s use of a staff member to discuss the surgery and options without his personal input places him in a difficult position. This informed consent practice does not ensure that the doctor has first-hand knowledge of the patient’s understanding of his condition, the options, and their medical and financial ramifications, which in turns limits his ability to address questions, build trust, and maximize patient endorsement. Even though staff can definitely answer, augment, and clarify the informed consent process, it is the surgeon’s responsibility to ensure that the patient has received enough information and time to give informed consent.

Second, misrepresentation of favorable outcomes is not in the best interest of this patient since his medical condition, type 2 diabetes, carries the possibility of diabetic retinal disease that could be vision limiting. This knowledge may have led the patient to question whether the more expensive packages were warranted.

Third, it is the physician’s duty to ensure that a surgical option is optimal for the patient’s condition. Although cataract extraction is indicated in a patient with cataract and impaired function, the offer to place a multifocal lens in someone in whom diabetic retinal disease has not been ruled out due to visualization or who has a high likelihood of developing it raises the issue of competence. Given the inconclusive retinal exam and/or the potential to develop diabetic retinopathy, a monofocal lens would be a safer choice for this patient.

Applicable Rules

"Rule 1. Competence. An ophthalmologist is a physician who is educated and trained to provide medical and surgical care of the eyes and related structures. An ophthalmologist should perform only those procedures in which the ophthalmologist is competent by virtue of specific training or experience or is assisted by one who is. An ophthalmologist must not misrepresent credentials, training, experience, ability or results.”

"Rule 2. Informed Consent. Informed consent is the process of shared decision-making between the ophthalmologist and the patient and must precede the performance of medical or surgical procedure. During the informed consent process, pertinent medical and surgical facts, and recommendations consistent with standard of care in medical/surgical practice must be presented in understandable terms to the patient or patient surrogate. Such information should include the indications, benefits, objectives, risks and possible complications of the procedure, alternatives to the procedure, and the potential consequences of no treatment. The operating ophthalmologist must personally confirm comprehension of this information with the patient or patient surrogate."

Rule 3. Research and Innovation. Research is conducted to provide information on which to base diagnostic, prognostic or therapeutic decisions and/or to improve understanding of pathogenesis in circumstances in which insufficient information exists. Research and innovation must be approved by appropriate review mechanisms (Institutional Review Board; IRB) and must comply with all requirements of the approved study protocol to protect patients from being subjected to or potentially affected by inappropriate or fraudulent research. In emerging areas of ophthalmic treatment where recognized guidelines do not exist, the ophthalmologist should exercise especially careful judgment and take appropriate precautions to safeguard patient welfare. Appropriate informed consent for research and innovative procedures must recognize their special nature and ramifications. The ophthalmologist must demonstrate an understanding of the purpose and goals of the research and recognize and disclose financial and non-financial conflicts of interest. Commensurate with the level of his/her involvement, the investigator must accept personal accountability for patient safety and compliance with all legal and IRB-imposed requirements."

"Rule 4: Other Opinions. Ophthalmologist should be cognizant of the limitations of his/her knowledge and skills and be willing to seek consultations in clinical situations where appropriate. The patient's request for additional opinion(s) should be respected."

"Rule 9. Medical and Surgical Procedures. An ophthalmologist must not misrepresent the service that is performed or the charges made for that service. An ophthalmologist must not inappropriately alter the medical record."

"Rule 10. Procedures and Materials. Ophthalmologists should order and/or utilize only those laboratory and surgical procedures, optical devices or pharmacological agents that are in the best interest of the patient. It is unethical to prescribe or provide unnecessary services and procedures or seek compensation for those services. It is equally unethical to withhold necessary services or procedures."

"Rule 13. Communications to the Public. Communications to the public must be accurate. They must not convey false, untrue, deceptive, or misleading information through statements, testimonials, photographs, graphics and other means. They must not omit material information without which the communication would be deceptive. Communications must not appeal to an individual's anxiety in an excessive or unfair way, and they must not create unjustified expectations of results. If communications refer to benefits or other attributes of ophthalmic procedures that involve significant risks, realistic assessments of their safety and efficacy must also be included, as well as the availability of alternatives and, where necessary to avoid deception, descriptions and/or assessments about the benefits or other attributes of those alternatives. Communications must not misrepresent an ophthalmologist's credentials, training, experience or ability, and must not contain material claims of superiority that cannot be substantiated. If a communication results from payment by an ophthalmologist, this must be disclosed unless the nature, format or medium makes it apparent."

Other References

Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services. 42 C.F.R. § 2.31 ("Consent Requirements"). Available at: https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=42%3A1.0.1.1.2.

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